

RESPONSE TO OFFICE ACTION

ATT'Y. DOCKET : RM.CH5
APPLICANT : Symington, et al.
US SERIAL NO. : 10/539,923
US ENTRY DATE : February 21, 2006
PCT SERIAL NO. : PCT/US03/01943
INT'L FILING DATE : December 16, 2003

Examiner : Benjamin J. Packard
Art Unit : 1612
Conf. No. : 90068399

REMARKS

Amendments and arguments are presented herein to improve the form of the subject application and in response to the Examiner's comments in the above-identified Office Communication.

Non-Responsiveness Under MPEP § 821.03

The Examiner states that the amendment filed on 12/29/08, amending all claims drawn to the elected invention and deemed by the Examiner to present only claims drawn to a non-elected invention is considered by the Examiner to be non-responsive (MPEP § 821.03). In this regard, the Examiner states that the remaining claims are not readable on the elected invention because while the elected invention was directed to a formulation, the newly amended claims appear to be directed to a system that includes both compositions and method of use steps, which according to the Examiner is not a statutory class. The Examiner directs Applicants' attention to MPEP 2106 and 35 U.S.C. 101. The Examiner concludes that the claims no longer appear to be properly directed to the elected formulation claims.

The Examiner continues the comment by stating that since the above-mentioned amendment appears to be a *bona fide* attempt to reply, Applicants are given a Time period of one (1) month or thirty (30) days, whichever is longer, from the mailing date of the Office Communication within which to supply the omission or correction in order to avoid abandonment.

APPLICANTS' RESPONSE

Applicants respectfully disagree with the conclusion reached by the Examiner and assert that the Examiner has not issued a clear rationale in support of the refusal to enter the present amendment.

As a preliminary matter, it is noted that the Examiner has intertwined in the Office Communication objection to the amended claims on the basis of non-readability on the elected claims with non-statutory class under 35 U.S.C. § 101. The actual and specific basis of the

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Examiner's objection to the amendments to the claims is confusing to Applicants as it is not clear whether the issue is one of claims being drawn to a non-elected invention, or whether the claims do not specify statutory subject matter under 35 U.S.C. § 101.

The foregoing notwithstanding, Applicants have amended the claims, without prejudice, to overcome the Examiner's objection, as understood. Since the amendment filed on 12/29/08 is presumed not to have been entered by the Examiner, the present amendments to the claims are based on original claims 1-8.

More particularly, amended claims 1-8 have been restored to specify a formulation, which is entirely consistent with the original election, and which clearly constitutes patentable subject matter under 35 U.S.C. § 101. It is therefore respectfully asserted that the Examiner's objections to the entry of the previous amendment on the grounds of the amended claims being drawn to a non-elected invention, or as not specifying statutory subject matter under 35 U.S.C. § 101, have been overcome.

Applicants assert that there is present in the specification support for a formulation comprised of a pharmacologically-active substance applied directly onto a surface of the tooth of the patient and a coating applied over the pharmacologically-active substance. In this regard, the Examiner's attention is respectfully directed to illustrative portions of the specification as follows:

Page 3, line 34 to page 4, line 6, the prior art is characterized as "...incorporating PMMA-type polymers in the oral cavity ... directed to one-stage drug delivery formulations, tablets or devices which combine the acrylic polymer, ... with an active drug substance." Clearly, the term "formulation" is known in the art to include an acrylic polymer in combination with an active drug substance.

Page 6, lines 14-16, states that "... a formulation in accordance with the present invention is applied to the surfaces of teeth to form a pharmacologically

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inert barrier coating over prior coating(s) containing pharmacologically-active substances." Thus, in the context of the present invention, as described in the specification, the term "formulation" comprises the inert barrier coating over the active substances.

For these and other reasons, it is respectfully asserted that the claims as amended herein specify subject matter that is consistent with the elected claims.

In addition to the foregoing, it is respectfully asserted that formulations constitute compositions of matter that clearly fall within the scope of patentable subject matter specified in 35 U.S.C. § 101. Accordingly, the Examiner's objection to the prior amendments as rendering the claims to be directed to a non-elected invention and/or to specify non-statutory subject matter has been overcome.

Claims Rejections

With respect to the prior rejection of the claims under 35 U.S.C. § 112, 35 U.S.C. § 102, and 35 U.S.C. § 103, Applicants incorporate herein the arguments proffered in the amendment filed on 12/29/08, as follows:

CLAIM 3 - 35 U.S.C. § 112

Claim 3 was rejected under 35 U.S.C. 112, second paragraph, by the Examiner as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because Claim 3 contains the trademark/trade name "EUDRAGIT RS 30 D."

According to the Examiner, the use of a trademark or trade name in a claim, as a limitation to identify or describe a particular material or product, does not comply with the requirements of 35 U.S.C. 112, second paragraph. In this regard, the Examiner directs Applicants' attention to *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The Examiner states that the claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name

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does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a specific formulation of polymethylmethacrylate copolymer and, accordingly, the identification/description is indefinite.

APPLICANTS' RESPONSE

M.P.E.P §608.01(v) states that the use of trademarks to identify products is acceptable provided the definition of the product is established in the specification by a definition, and the product is well-known and defined in the literature. In fact, Appendix I of the M.P.E.P. provides a partial list trademarks that are known and acceptable for use in patent applications.

The EUDRAGIT family of polymethylmethacrylate coating lacquers, produced by Rohm Pharma, are well-known in the art for use as excipients in sustained release and transdermal drug delivery systems, and comply with the US Pharmacopia and National Formulary. Therefore, the composition marketed under the EUDRAGIT trademark is sufficiently defined and definite to meet the requirements of the patent law and related regulations. More specifically, Applicant has provided in the specification a definition of the product and a cite to the Rohm Pharma website that sets forth the composition and characteristics of this particular EUDRAGIT compound. See, page 2, lines 24-25, particularly line 33; page 5, lines 19-27. Therefore, it is respectfully asserted that the use of EUDRAGIT RS 30D as a trademark in claim 3 does not render the identification or specification of the claimed composition to be indefinite.

In addition to the foregoing, it is specified in the claims themselves, specifically dependent claim 3, that the ammonio methacrylate copolymer is EUDRAGIT RS 30 D brand polymethylmethacrylate. Thus, Applicants are not baldly identifying the copolymer by a trademark, but instead is identifying the trademark product as "ammonio methacrylate copolymer" and as a "polymethylmethacrylate." Thus, the identification of a well-known trademark (EUDRAGIT) in the specification, and the additional specification of the trademarked material in the claims themselves renders Applicants' use of the mark to be acceptable and within the guidelines established in M.P.E.P §608.01(v) and therefore in conformance with 35 U.S.C. § 112.

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In view of the foregoing, it is respectfully asserted that the Examiner's rejection of dependent claim 3 under 35 U.S.C. § 112, second paragraph, has been overcome.

CLAIMS 1-8 - 35 U.S.C. § 102(B)

Claims 1-8 were rejected under 35 U.S.C. § 102(b) as specifying subject matter considered by the Examiner to be anticipated by U.S. Patent No. 5,286,497 issued to Hendrickson, *et al.* (hereinafter "Hendrickson, *et al.*").

The Examiner stated that the Hendrickson, *et al.* reference discloses a method of making a polymeric formulation comprising a mixture of water, EUDRAGIt RS 30 D and plasticizer (see, Col. 12, lines 46-58). Among the disclosed plasticizers is triethyl citrate. The amount plasticizer utilized can vary, but will typically be present in the amount of 0 to 40 w/w %, and more preferably about 5-15 w/w % (Col. 7, lines 16-28). Further, the Examiner alleged that with respect to the plasticizer, triethyl citrate, where selection of one named species from a list of alternatives is all that is required to arrive at the instantly claimed subject matter, that species is anticipated, citing *Ex Parte A.*, 17 USPQ2d 1716 (Bd. Pat. App. Inter. 1990); *In re Sivaramakrishnan*, 213 USPQ 441 (CCPA 1982).

The Examiner pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the Examiner contended that the intended use of an inert coating to serve as a temporary mechanical barrier on top of a temporary coating of pharmaceutically-active substance applied to the surface of a tooth appears to be met where the prior art teaches the polymeric formation as a coating for an active substance. The physical properties, such as viscosity, would have been reasonably expected by the Examiner to be inherent, on the ground that the concentration of components of the disclosed solution appear to the Examiner to be of substantially the same range as those disclosed in the instant specification.

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APPLICANTS' RESPONSE

Applicants have amended independent claim 1 to specify a system of a coating applied over a pharmacologically-active substance that is itself installed to be in direct communication with a surface of a tooth of a patient. Nothing in the Hendrickson, *et al.* reference teaches or suggests a formulation that comprises this combination of elements.

In view of the foregoing, independent claim 1 is respectfully asserted by Applicant to specify subject matter that is patentable distinguishable over the teaching in the Hendrickson, *et al.* reference. Claims 2-8, which are also subject to this rejection, all depend from amended independent claim 1 and therefore contain all of the limitations therein. Accordingly, the Examiner's rejection of claims 1-8 under 35 U.S.C. § 102(b) has been overcome.

CLAIMS 1-8 - 35 U.S.C. § 103(A)

Claims 1-8 were further rejected under 35 U.S.C. § 103(a) as specifying subject matter considered by the Examiner to be obvious over the Hendrikson, *et al.* reference.

The Examiner argued that, assuming that the prior art differs from the instant claims insofar as it does not suggest the composition as a preferred embodiment, it still would have been obvious to one skilled in the art to pick and choose among the disclosed plasticizers, where the various options are disclosed, to provide the same physical property to the solution.

APPLICANT'S RESPONSE

As noted above, independent claim 1 has been amended to specify subject matter that is neither taught or suggested by the Hendrikson, *et al.* reference, or any of the references of record, irrespective of whether they are viewed singularly or in combination. Dependent claims 2-8 depend from amended independent claim 1, and therefore contain all of the limitations therein. In addition, dependent claims 2-8 have been amended to specify proper antecedent basis in conformance with the amendments herein made to independent claim 1. Accordingly, it is respectfully asserted that the Examiner's rejection of claims 1-8 under 35 U.S.C. § 103(a) has been overcome.

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Conclusion

In view of the foregoing, it is respectfully requested that the Examiner reconsider the present application, allow the claims, and pass the application for issue. If the Examiner believes that the prosecution of this case can be expedited by a telephone interview, the Examiner is requested to call attorney for Applicant at the telephone number indicated hereinbelow.

Respectfully submitted,



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RAM:rb:ROA-Comm.CH5

enc Annexure 1 - Claims Rewritten to Show Amendments
File: ROA-Comm.CH5